

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
14 October 2004 (14.10.2004)

PCT

(10) International Publication Number
WO 2004/087173 A3

(51) International Patent Classification⁷: **A61K 31/7032**,
A61P 29/00, 3/06

(21) International Application Number:
PCT/CA2004/000375

(22) International Filing Date: 12 March 2004 (12.03.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/404,095 2 April 2003 (02.04.2003) US

(71) Applicant (for all designated States except US): **MTI
META TECH INC.** [CA/CA]; 11249 University Avenue,
Edmonton, Alberta T6G 1Y7 (CA).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CLANDININ,
Michael, Thomas** [CA/CA]; R.R.#4, Calmar, Alberta
T0C 0V0 (CA). **PARK, Eek, J.** [KR/CA]; #846, 11121-82
Avenue, Edmonton, Alberta T6G 0T4 (CA).

(74) Agents: **SILVER, Gail, C. et al.**; Borden Ladner Gervais
LLP, World Exchange Plaza, 100 Queen Street, Suite 1100,
Ottawa, Ontario K1P 1J9 (CA).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), Euro-
pean (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,
GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
25 November 2004

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: FORMULATIONS FOR MEDIATING INFLAMMATION AND FOR REDUCING BLOOD CHOLESTEROL

(57) Abstract: The invention provides formulations for mediating inflammation and for lowering blood cholesterol. For example, inflammation of the intestine, retina or neural tissues, may be mediated. Further the formulations are effective in decreasing blood cholesterol absorption. The formulations comprise at least one ganglioside, which may be selected from the group consisting of: GD3, GM1, GM2, GM3, GD1b, NANA, and sialic acid. The invention further provides a method of treating or preventing inflammatory diseases by delivery of at least one ganglioside to a subject in need thereof, and a method of reducing blood cholesterol in a subject by delivery of a ganglioside-containing formulation. The formulation of the invention may be used to supplement foods or liquids, and may for example be used in preparation of infant formula or foods.

WO 2004/087173 A3

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA2004/000375

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/7032 A61P29/00 A61P3/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, PAJ, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	BUCOLO C ET AL: "EFFECTS OF MIPRAGOSIDE ON OCULAR ALLERGIC INFLAMMATION IN THE RABBIT" JOURNAL OF OCULAR PHARMACOLOGY, MARY ANN LIEBERT, INC. NEW YORK, NY, US, vol. 9, no. 4, 1993, pages 321-332, XP000570599 ISSN: 8756-3320 page 321, abstract	1-6, 10-18
X	EP 0 351 784 A (FIDIA SPA) 24 January 1990 (1990-01-24) claims 1,2 ----- -/--	1-3,5,6, 10-12, 14-18

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

30 June 2004

Date of mailing of the international search report

11. 10. 2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Beranová, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA2004/000375

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	OLIVEIRA ALEXANDRE L R ET AL: "GM-1 ganglioside treatment reduces motoneuron death after ventral root avulsion in adult rats" NEUROSCIENCE LETTERS, vol. 293, no. 2, 27 October 2000 (2000-10-27), pages 131-134, XP002286616 ISSN: 0304-3940 page 131, abstract	1-3,5,6, 10,12, 14-18
X	----- WO 95/20959 A (US ARMY) 10 August 1995 (1995-08-10) claims 1,5	1,3,5,6, 10,12, 14,15, 17,18
X	----- GB 2 289 274 A (ERBA CARLO SPA ; PHARMACIA SPA (IT)) 15 November 1995 (1995-11-15) claim 1 page 7, line 11	1,3,5,6, 10,12, 14,15, 17,18
X	----- DATABASE WPI Section Ch, Week 198931 Derwent Publications Ltd., London, GB; Class A96, AN 1989-225642 XP002286617 & JP 01 163125 A (SHISEIDO CO LTD) 27 June 1989 (1989-06-27) abstract	1,3,5,6, 10,12, 14,15, 17,18
X	----- WO 90/09185 A (ANGIO MEDICAL CORP) 23 August 1990 (1990-08-23) claims 1,5 -----	1,5

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-18

Use of gangliosides for the treatment of inflammation

2. claims: 19-28

Use of gangliosides for reducing plasma cholesterol

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2004/000375

Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 19-28
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 10 - 14 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-18

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claims 10 - 14 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA2004/000375

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0351784	A	24-01-1990	IT 1224513 B AT 97812 T AU 624164 B2 AU 3819089 A DE 68911049 D1 DE 68911049 T2 DK 354589 A EP 0351784 A2 ES 2061821 T3 JP 2078622 A PH 26117 A ZA 8905367 A	04-10-1990 15-12-1993 04-06-1992 25-01-1990 13-01-1994 01-06-1994 20-01-1990 24-01-1990 16-12-1994 19-03-1990 24-02-1992 25-04-1990
WO 9520959	A	10-08-1995	US 5631283 A WO 9520959 A1 US 6066323 A	20-05-1997 10-08-1995 23-05-2000
GB 2289274	A	15-11-1995	NONE	
JP 1163125	A	27-06-1989	JP 2684179 B2	03-12-1997
WO 9009185	A	23-08-1990	AU 5160590 A WO 9009185 A1	05-09-1990 23-08-1990